

EXHIBIT B

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF CALIFORNIA

3 HONORABLE ANTHONY J. BATTAGLIA, JUDGE PRESIDING
4

5 IN RE INCRETIN-BASED THERAPIES)
6 PRODUCTS LIABILITY LITIGATION)
7)

8 THIS DOCUMENT RELATES TO ALL CASES)
9)

10 Reporter's Transcript of Proceedings
11 Status Conference

12 Appearances:

13 For the Plaintiffs:

14 RYAN THOMPSON
15 TOR HOERMAN
16 HUNTER J. SHKOLNIK
17 MIKE JOHNSON
18 MAX KENNERLY
19 KEN PEARSON
20 GAYLE M. BLATT
21 LIBERTY EDWARDS

22 For the Defendant Novo Nordisk:

23 HEIDI LEVINE
24 LEEANNE NERI
25 CHRISTOPHER YOUNG

For the Defendant Eli Lilly And Company:

NINA GUSSACK
KENNETH KING

For the Defendant Amylin Pharmaceuticals LLC:

RICHARD GOETZ
HOUMAN EHSAN

Appearances cont'd

1 For The Defendant Merck:

2 DOUGLAS MARVIN
3 PAUL BOEHM
4 ANA REYES
5 VICKIE TURNER

6 For the Defendant Eli Lilly And Company:

7 STEVE SWINTON
8 GEORGE LEHNER
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1 San Diego, California, February 18, 2014

2
3 THE CLERK: Number 1 on calendar, 13-MD-2452, In
4 Re Incretin Mimetics Products Liability Litigation
5 on for status conference.

6 THE COURT: Well, good morning, all. I think
7 what I'll do in the interest of expediency is from
8 the list that was created just identify who all is
9 here, and then if someone comes in late, they can
10 speak up, and we can add them to the list.

11 And the list for no particular reason
12 starts with defense counsel, so let me start there.

13 We've got Heidi Levine for Novo Nordisk,
14 Nina Gussack and Kenneth King for Eli Lilly, Richard
15 Goetz for Amylin Pharmaceutical, Douglas Marvin,
16 Paul Boehm, Ana Reyes, and Vickie Turner for Merck,
17 George Lehner for Eli Lilly, Houman Ehsan for Amylin
18 Pharmaceuticals, Leeane Neri for Novo Nordisk,
19 Christopher Young for Novo Nordisk, Steve Swinton
20 for Eli Lilly Company.

21 Any other defense folk that I've missed?
22 Nobody speaks up, so that's good.

23 For the plaintiffs Ryan Thompson, Tor
24 Hoerman, Hunter Shkolnik, Mike Johnson, Max
25 Kennerly, Ken Pearson, Gayle Blatt, Liberty Edwards.

1 Did I miss anybody?

2 MR. SHKOLNIK: That's all, Your Honor.

3 THE COURT: Okay, great.

4 So we're here for status case management,
5 and I have spent many hours going through your
6 submissions and considered them very carefully, and
7 I have questions I don't think either of you will
8 like. I have a hybrid situation in mind, but it's
9 dependent upon the answer to some questions.

10 Now, let me address this to the defense
11 first. The plaintiffs are saying that they don't
12 have the benefit of all discovery, in particular the
13 clinical trial information, so they can test in a
14 sense the bona fides of all that body of data with
15 regard to a potential causative link between the
16 drugs and pancreatic cancer. And that concerns me
17 because if that is true, it would seem that the
18 defense is suggesting we take their word for the
19 essence of the results of the data and challenge the
20 plaintiffs' proposition on that basis alone.

21 So -- and you can pick who you want to have
22 address it, folks, but I mean is it true that not
23 all clinical information has been made available?

24 And Ms. Gussack.

25 MS. GUSSACK: Thank you, Your Honor.

1 No, that's not true, although it's not
2 complete, so let me go back a step and say all of
3 the defendants have produced their Investigational
4 New Drug and New Drug Applications, and those are
5 the regulatory submissions that the pharmaceutical
6 manufacturers make to FDA to support the
7 preclinical, the animal testing, and the clinical
8 trials testing done in humans. And just speaking
9 for the Byetta defendants, I can tell you in our
10 IND/NDA production the plaintiffs have at their
11 disposal data from 58 completed clinical trials, 47
12 final clinical study reports, 88 clinical study
13 protocols, much toxicology animal data, adverse
14 event reports, compilations of periodic safety
15 update reports, and all of the communications to and
16 from FDA about Byetta.

17 In addition, for Byetta defendants, Your
18 Honor, the plaintiffs have had the benefit of both
19 the production that was made in the JCCP, which was
20 4.5 million documents, and then an additional
21 2 million documents which come from key custodians
22 who are involved in safety, regulatory, medical --
23 did I say documents? I meant pages. Pages.
24 6.5 million pages. And these custodians are in the
25 core areas where clinical trial data would be

1 discussed, evaluated, and being commented on.

2 But I think it's fair to say, Your Honor,
3 from the defendants' perspective, speaking a little
4 bit more broadly, it is not the defendants' view
5 that general causation is now ready to be heard
6 because all discovery is concluded. The defendants
7 fully contemplated that some additional discovery
8 that could be defined by some reasonable scope
9 should occur and that the critical issue that the
10 defendants are advancing here, Your Honor, is that
11 the priority in the case management order should be
12 directed towards the issue of whether these agents
13 are capable of causing pancreatic cancer as opposed
14 to leaving it to the end of the path.

15 THE COURT: Okay. And what don't they have
16 then -- if you were on the plaintiffs' side, what
17 would you be asking that they haven't gotten in this
18 litany of data? Is there anything else is the
19 question.

20 MS. GUSSACK: Well, Your Honor, I would say that
21 as a plaintiff, looking to frame this issue, both
22 cost effectively and with targeted focus on the
23 science, I would both evaluate that I had the
24 clinical trial data, I have access to an enormous
25 amount of published data, and I might then in a

1 focused way ask for -- to confirm that I had the
2 full array of studies and analyses of ongoing
3 studies. There may well be some reasonable
4 additional information.

5 I have to say, Your Honor, of all the
6 questions I could have anticipated, asking me to be
7 a plaintiff for the day was not one of them, but I
8 will, putting on their hat for a moment, recognize
9 that there is some -- I'm sure some additional scope
10 that they could test, and, in fact, questions could
11 be asked really quite narrowly, which is do you have
12 any data that demonstrates, supports that the
13 incretin-based medicines caused pancreatic cancer.

14 But I think that what we are faced with
15 right now is extremely broad-based discovery.
16 Nonetheless, the parties have been responding and
17 continue to respond to discovery requests.

18 THE COURT: Okay. And so that's where we stand
19 with Lilly.

20 Ms. Levine, how about with Novo Nordisk?

21 MS. LEVINE: Thank you.

22 We agree wholeheartedly with Ms. Gussack's
23 statements. Similarly, the Novo Nordisk defendant
24 has produced its initial drug application and New
25 Drug Application, which is more than 1.4 million

1 pages of data. It includes 209 preclinical or
2 animal studies, 54 clinical studies, and all of the
3 communications with the FDA, but we are in the
4 process of speaking with the plaintiffs, in fact
5 meeting with them this afternoon, to discuss the
6 parameters of additional discovery. And you've
7 asked that question, and I'll address it, which is
8 we've prepared a study chart that includes all of
9 the completed and ongoing clinical and nonclinical
10 trials for the plaintiffs, which is probably more
11 than we had to do, protocols, final study reports,
12 raw data sets to be discussed in a meet and confer,
13 adverse event reports.

14 As you can imagine, Novo, who got into the
15 litigation several months later than some of the
16 other defendants and are a little bit later in the
17 production of adverse event reports, but we are in
18 the process with our client of obtaining them,
19 making productions, and having very productive and
20 fruitful discussions with plaintiffs, SOPs and other
21 things that plaintiffs may ask for. We're
22 absolutely ready and willing to produce additional
23 discovery. We think that it is reasonable for
24 plaintiffs to ask for additional discovery, but what
25 we want is to have a general fact -- a general

1 causation fact discovery cutoff that addresses these
2 key issues up front to encourage the plaintiffs to
3 focus on what the real general causation discovery
4 issues that they need rather than dealing with all
5 of the other types of fact discovery that one might
6 see in a typical MDL, which this is not.

7 THE COURT: Okay. All right. Well, thank you.

8 And how about Mr. Goetz and Amylin?

9 MR. GOETZ: Thank you, Your Honor.

10 Amylin and Lilly jointly produced much as
11 what Ms. Gussack said would apply to Amylin as well.
12 we've offered to produce additional materials.
13 There are some costs associated with that that I'm
14 not sure that plaintiffs want to invest to make
15 copies of some slides, but we've made that offer
16 back in October. Dr. Ehsan behind me can answer
17 questions if that comes up.

18 A lot of the recent discovery has focused
19 on things other than what Your Honor raised. Not
20 clinical studies, but, "Can you give me backup data
21 on adverse event reports so that I can see if you
22 properly coded a pancreatic cancer case or not?"
23 And we've been responsive on that. We've produced
24 two witnesses last week who were deposed for seven
25 hours. 15 witnesses were deposed on those subjects

1 in the JCCP proceedings. And last year we gave the
2 plaintiffs in these proceedings an index that showed
3 by line and page number where those witnesses
4 testified about adverse event reports.

5 The one thing those 15 witnesses have in
6 common is that after Bristol Myers acquired Amylin
7 and moved most people to New Jersey, those people
8 decided to stay in Southern California. I can tell
9 you trying to get out of Newark airport last week, I
10 understand why, but they don't work for us anymore,
11 and so we're trying to get a supplemental witness
12 who can testify about adverse event reports prior to
13 April of 2013 when Bristol Myers took over handling
14 those, and we committed that we will.

15 That's going to require us to find somebody
16 who's willing and able to testify, but the focus
17 hasn't been recently on the clinical studies because
18 I think they have what they need on that, and we're
19 willing to produce additional documents and
20 supplements and updates as necessary, but we agree
21 with both Ms. Levine and Ms. Gussack that we ought
22 to move this to the forward of this general
23 causation issue.

24 THE COURT: And then Mr. Marvin for Merck.

25 MR. MARVIN: Good morning, Your Honor.

1 Ten months ago, last April, Merck produced
2 over 382,000 pages plus 2.29 gigabytes of data. I'm
3 not really sure what a gigabyte is, but I know --

4 THE COURT: It's a lot.

5 MR. MARVIN: -- it means "giant" in Greek.

6 And as part of that production, it means
7 that we've produced preclinical studies -- over 85
8 preclinical studies, more than 100 clinical studies.
9 That's also included protocols, investigators'
10 brochures describing the safety profile, statements
11 of the investigators, safety reports. We've also
12 produced the adverse event reports that are provided
13 to the FDA on the Medwatch forms that they require.
14 On observational studies, the plaintiffs have the
15 Eurich study, which included over 8,000 Januvia
16 patients, and the Gokhale study, which was over
17 100,000 patients, about 30,000 which were taking
18 DPP-4s, and we've produced the regulatory file which
19 includes the labeling history, and the
20 correspondence with the FDA for more than 12 years.

21 Your Honor, when we were considering the
22 production, we purposefully looked at what it is
23 that scientists really look at in making these
24 determinations about the causation, and that's why
25 we produced this information more than ten months

1 ago. It was for that very purpose.

2 So I join with my colleagues in saying that
3 the studies and the type of information that
4 scientists look at has been produced, and if there's
5 something else out there that's targeted that the
6 plaintiffs want, then we're happy to talk to them
7 about providing that.

8 THE COURT: Okay. Well, let me then turn to the
9 plaintiffs' side, and you can pick your initial
10 spokesperson. If you want to have somebody
11 supplement, you may, but it sounds like you have a
12 lot of data and focus on this issue of general
13 causation, this clinical information, so forth.
14 Other than maybe some discussion of backup data for
15 the adverse reports or something else of a small
16 degree or other degree or reproduction and the cost
17 of reproduction of slides, what else do you need for
18 that particular issue? Anybody?

19 MR. JOHNSON: Your Honor, good morning. Mike
20 Johnson on behalf of the plaintiffs.

21 THE COURT: Thanks, Mr. Johnson. Go ahead.

22 MR. JOHNSON: Thank you.

23 Your Honor, I'm chair of the discovery
24 committee, and if I can docket this issue for a
25 moment. It is true at the moment the defendants

1 have given us some production, and they have told us
2 that they have given us their IND and their NDA.
3 what we have not yet heard from them is that it is
4 a -- that it is a complete production. And in fact,
5 we've gotten a letter from -- as recent as last week
6 from Amylin with respect to some of the information
7 that they've given to the FDA and said, "You know
8 what? We're not positive what we've given you today
9 is" -- and this is with respect to the adverse event
10 reporting -- "we aren't exactly certain if this is
11 everything we have or not. We need to go back and
12 take a closer look at it."

13 So two things. Not only have the
14 defendants not told us that their production has
15 been complete yet, but second, they don't seem to
16 yet know if their production is complete.

17 But beyond that I want to just talk a
18 little bit about where we've been in discovery
19 because I think that there's a little broader issue
20 here than just the IND and the NDA.

21 As Your Honor may know, a lot of times
22 these cases turn on not what was given to the FDA,
23 but what was not given to the FDA. And what we
24 haven't had yet is an opportunity to test what they
25 have given us.

1 So, for example, we've gone through some of
2 the documents that they've given us, and we were
3 told on Science Day that there was no signal for
4 pancreatic cancer in any of the early clinical
5 trials.

6 Well, as we've gone through some of the
7 documents, we have found cases of folks who were in
8 their clinical trials that developed pancreatic
9 cancer that were -- that appeared to be excluded.
10 we need to test that in discovery. "What exactly --
11 so we have your INDs and we have your NDAs, but what
12 exactly were the parameters for your clinical and
13 your preclinical trials? In other words, how did
14 you decide who got excluded and who didn't?"

15 And when we're talking about a case that
16 involves pancreatic cancer with a very low incidence
17 rate, one or two proper exclusions can very quickly
18 shift the incidence rate and make a signal look much
19 bigger.

20 And right now, Your Honor, what they're
21 really doing is they're saying, "Hey, look. We're
22 telling you what we've given the FDA. That's enough
23 to do your job."

24 And what we're saying, Your Honor, is, "We
25 need to figure out what wasn't given to the FDA, and

1 we need to test what it is you've given to the FDA."

2 THE COURT: As far as these parameters, these 15
3 or so depositions that were taken, they didn't
4 address that aspect or that question? They were
5 more specific to data, period?

6 MR. JOHNSON: Yes. And to be clear, there
7 weren't 15 depositions taken in this case. There
8 have only been three.

9 THE COURT: But the sum total of the depositions
10 that have been taken to date didn't touch on how you
11 decided who is in and who's out?

12 MR. JOHNSON: Your Honor, those depositions, if
13 you'll recall, are from the JCCP, and they dealt
14 with pancreatitis and not pancreatic cancer. And so
15 to the best of my knowledge, those specific
16 questions were not addressed.

17 And so if I could just step back a moment,
18 Your Honor, I just want to talk about where we are
19 in the big scope of discovery because if you were to
20 listen to the defendants, you would think, "Well, my
21 gosh, they really have -- you know, they really have
22 given us a lot here."

23 But when the MDL was formed in this case,
24 Your Honor, what we did is we took all the pre-MDL
25 discovery, and we condensed it into a few different

1 sets so that we had just a couple workable sets for
2 everybody to work off of. We started serving those
3 sets in November.

4 Around December we got a phone call, and
5 they said, "Hey, the holiday's coming up. What we
6 would really like is an extension until after the
7 holidays." And we said -- "to answer." And we
8 said, "That is not a problem." We gave all the
9 defendants an extension until mid-January to answer,
10 and for the first time when we received their
11 answers we were told, "Guess what? You're not
12 getting any answers. What you're going to get is
13 you're going to get absolute blanket objections, and
14 we're objecting because we think that you have asked
15 too many questions." We've negotiated for the last
16 four to six weeks on limitations with respect to
17 written discovery, and the CMO was introduced -- or
18 excuse me, was filed for your signature this morning
19 that limits and sets the limits on discoveries.

20 With that agreement in place, Your Honor,
21 the defendants served their answers to
22 interrogatories for the first time on Friday and
23 their answers to requests for productions this
24 Monday.

25 And just to give you -- I want to give you

1 a very micro example of what we've received so far,
2 and then I'll give you a macro example.

3 You heard a lot in Science Day that the EMA
4 is one of the things that makes this case unique
5 from other cases. We asked them a question in our
6 discovery, and we said, "Hey, tell us about your
7 interactions with the EMA. What did you provide
8 them? Was anybody from your company on their
9 panel?"

10 What they told us, Your Honor, is, "We're
11 not going to answer that. The EMAs are irrelevant
12 to this case, and it's not reasonably calculated to
13 lead to admissible discovery."

14 And that, I think, is just the most
15 poignant example of what it is that we're sort of
16 dealing with at this point.

17 And so let's talk about this from a macro
18 perspective. And I'm going to talk about Novo for
19 just a minute, not to pick on them, not to single
20 them out, but only because they kind of took the
21 lead on the discovery issues for the defendants.

22 Of the 54 interrogatories, 16 of them -- or
23 30 percent of them their answer was, "We'll answer
24 later." 15 of the 54, which is 28 percent, there's
25 a complete objection and a refusal to answer. 23 of

1 them, which is 43 percent, there's a partial answer,
2 which is -- with just a handful of complete -- with
3 just a handful of what we think are complete
4 answers, but we haven't had a chance yet to sit down
5 and meet and confer.

6 So Your Honor, we're just at the very tip
7 of the iceberg in terms of getting the discovery in
8 this case to figure out what is it they didn't give
9 the FDA and can we test what it is they claim that
10 they've given the FDA today.

11 THE COURT: Okay. And then while I've got you
12 at the podium, that begs the next question, although
13 I'll give the defense a chance to respond to this --
14 don't get nervous -- but as far as -- I mean in my
15 view, frankly, we ought to get to the bottom of the
16 general causation issue and focus the resources and
17 the time on that and leave for shortly thereafter
18 these other noncausation-related issues or issues
19 specific to any particular bellwether questions with
20 regard to misrepresentation or so forth,
21 representation, misrepresentation, and why is it the
22 plaintiffs don't see that either the cost savings or
23 the economy in doing that? I mean we may end up at
24 the end of the day there's a question of fact on
25 general causation, and then we at least know that

1 and off we go. You might end up with one side or
2 the other prevailing, and that opens up options.
3 why not focus it, as the defense urges -- and I'm
4 not saying that they're right and you're wrong on
5 the completeness of discovery. I'll hear from them
6 on that, but why shouldn't we get to these essential
7 questions, which cuts across the four drugs, and I'm
8 assuming in that statement that there's no distinct
9 difference in this issue between the GLP -- the
10 GLP-1s and the DPP-4s. Maybe there is, but I'm
11 assuming that we can deal with all of that. We put
12 that issue either behind us or we know some jury's
13 going to have to -- or series of jurors is going to
14 have to decide that. why does that make the
15 plaintiffs uncomfortable when we talk about those
16 kind of things? And I'm divorcing from that issues
17 as to who is in, who is out, what was said or not
18 said with regard to the clinical data and the FDA.
19 we're talking about to the public and these other
20 things that seem to be occupying a lot of your time
21 right now and may, since they're going on
22 concurrently, be slowing down the completeness of
23 the causation-related discovery as they're about to
24 throw up multiple balls in the air. That's a long
25 question I know, but do your best with it.

1 MR. JOHNSON: Your Honor, ultimately we are
2 comfortable getting into that decision. We think
3 the science is there for us now, and we think the
4 science is getting stronger. It's just an issue of
5 timing and completeness, and all that we're asking,
6 Your Honor, for is to give us the time to complete
7 the discovery. And I don't really see it as a cost
8 savings, and here's why. If you take their
9 example -- and we have to have our expert reports
10 done in April. Well, if you consider the lay of the
11 land that I just gave Your Honor with respect to
12 discovery, we're really not going to have a whole
13 lot of foundational material to give to our experts,
14 so we're going to give them our expert report that's
15 lacking some foundation just because we haven't
16 gotten it yet. And then as we get it, we're going
17 to have to give it to our experts, and they're going
18 to have to do an updated report. We're going to get
19 additional discovery. We're going to have to give
20 it to our experts. They'll have to do another
21 updated report and so on and so on and so on, and I
22 don't see the -- I think that's a false cost savings
23 that they're trying to sell here. I think it's
24 actually more work.

25 THE COURT: And I'm not focused so much on their

1 proposed dates. It's more their concept that we
2 deal with the general causation and then move on.

3 So if we assume that their discovery
4 becomes complete, then moving on to dealing with
5 general causation, the Dauberts and summary
6 judgments associated with that, and then stepping
7 from there to complete all other generic discovery
8 wouldn't be disadvantage to the plaintiffs as long
9 as you have enough time on the front end to be able
10 to give your experts a complete package. They can
11 do a report for a deposition, and we can have a
12 motion, right?

13 MR. JOHNSON: That's not necessarily accurate,
14 Your Honor. Sometimes, for example, let's say we
15 said, "Okay. Marketing is not part of the case.
16 It's not part of the general causation story."
17 Well, we all know from our experience in MDLs that
18 oftentimes marketing, quote, unquote, runs science,
19 and so sometimes we find our best documents in the
20 marketing. And so, for example, we might find that
21 there's a lot of chatter between marketing and the
22 scientists going on about early signal detection and
23 what that might mean with respect to a label, and in
24 addition in this case, and I think that you heard in
25 Science Day originally when these compounds were

1 discovered, the manufacturers thought that this was
2 going to be an absolute cure for diabetes. Not just
3 a treatment, but a cure. And so you have to imagine
4 in this case that there is some discussion about
5 these early science findings with the marketing
6 department. My point is the departments are
7 interrelated, and sometimes the best documents
8 aren't necessarily just coming out of the science
9 department.

10 THE COURT: I understand, but if we talk about
11 completeness of the clinical and other scientific
12 data is including signal detection related
13 communications or documents, that would seem to get
14 at the full on marketing plan, wouldn't it?

15 MR. SHKOLNIK: If I could add one point to help
16 us clarify what is being suggested, we -- the
17 defendants have -- and this is an issue that was
18 brought before Judge Dembin -- sought and are
19 looking to do extensive plaintiff-specific
20 discovery. They want every plaintiff's fact sheet
21 done in a timely fashion. They want all medical
22 records. They want to do full bore, what I call,
23 case-specific discovery, yet at the same time
24 they're suggesting from the plaintiffs' side, "Focus
25 your discovery just on general liability." It just

1 seems problematic that they want their cake and eat
2 it too here.

3 THE COURT: But that's a good point.

4 MR. SHKOLNIK: And they fought hard and now tie
5 our hands.

6 THE COURT: I understand that, but my question
7 is maybe "general causation" is a bad term because
8 it's vague, but I mean if we focus specifically on
9 the science and the potential cause of pancreatic
10 cancer or perhaps acceleration, who knows where this
11 all goes based upon the use of these drugs, and we
12 come to some either conclusion or the conclusion
13 that there's a triable question of fact, we've come
14 a long way in putting to bed probably the bigger --
15 one of the bigger parts of the cause, haven't we?

16 MR. KENNERLY: Max Kennerly, cochair of the law
17 committee, which is why I thought I'd step in on
18 this one. Our concern off of this is the practical
19 implications of trying to divorce out general
20 causation and discovery versus -- or science
21 discovery, however you frame it, from everything
22 else. Now, Your Honor, present for the first
23 deposition, we had -- we were trying to find out
24 communications with the FDA. We had numerous
25 speaking objections, numerous instructions not to

1 answer. Of the little bit of information we got out
2 of the representative from Merck, they couldn't tell
3 us which department in there was actually
4 responsible for reporting information to the FDA.
5 And this is one of their own regulatory affairs
6 officers.

7 This is the problem, Your Honor, is that if
8 we -- if Your Honor -- and there's an order that
9 says, "well, we're going to do just science now, not
10 stuff that's separate from science," then what we're
11 going to have at every single deposition is a bunch
12 of objections trying to push us in saying, "well,
13 this is science. That's not science." We're going
14 to have this in our document requests. We're going
15 to have this in our interrogatories. And what we
16 know from these cases is this stuff all mixes
17 together.

18 If we had looked at Merck back with Vioxx,
19 the decisions to actually conceal this information
20 about the trial studies didn't come from within the
21 science department. It actually came from higher
22 up, which then put the order back down telling them,
23 you know, we're not going to go with that study,
24 we're not going to approve it that way. We already
25 see in patients in this and what we have from

1 available data -- we have documents from Amylin
2 there's a 45-year-old man develops pancreatic cancer
3 after taking Byetta for 791 days. He's kicked out
4 of the trial for reflux. Now, who do we talk to
5 about that? Is this a science question or a
6 vigilance question? would this run into the
7 regulatory affairs if they were required to report
8 it?

9 This is going to be the problem, Your
10 Honor. We're already expecting to be here a lot.
11 Long objections. We've received pretty much nothing
12 but objections. The last deposition we did last
13 week, the representative they produced said, "I'm
14 not available to talk about anything prior to
15 October 2013." well, that's the bulk of the case is
16 prior to that. Essentially every plaintiff who's
17 filed took the drug before then, and so we're going
18 to have huge problems with a big stream of
19 objections that "That's not really science based,
20 that's something else."

21 So that -- that's where we are on that,
22 Your Honor. We're going to have disagreements, and
23 I take an example from the defendants. They said,
24 "well, you know, why don't you ask us what we think
25 we have in our file shows pancreatic cancer?" well,

1 we know the answer. They're going to say, "Nothing
2 does. Nothing shows pancreatic cancer."

3 From Merck they cited in the clinical trial
4 summary the Engel study, which they said pooled
5 together the trials and showed no pancreatic cancer.
6 They left out Clinical Trial P28 where there was
7 somebody with pancreatic cancer. Put that one back
8 in there and completely change the statistics.

9 Here's our request: Are we going to be
10 back in front of Your Honor or in front of
11 Judge Dembin every week talking about whether
12 something is science related or not science related?

13 THE COURT: And I appreciate that, and here the
14 defendants tell it right now much of what you're
15 dealing with is noncausation or general causation
16 issues in terms of discovery requests. Is that
17 fair? Is that a fair statement?

18 MR. KENNERLY: I wouldn't say so, Your Honor. I
19 would say our requests are broad. The defendants
20 themselves sought to severely limit the number of
21 requests that we could have, so we have requests on
22 the whole plethora of issues that could come out.
23 That's what we're operating off of. That's what the
24 case management order was. So to the extent we're
25 asking other issues, well, yes, thus far we're under

1 a general scope of discovery.

2 In terms of what we've been trying to get
3 more details out of, the types of depositions we've
4 noticed, the types of depositions we've discussed
5 with them, the focus of the ESI, this is -- there's
6 a science basis on it, but, again, the question is
7 how do you divorce the two from each other? What
8 would change about the ESI? What would change about
9 the depositions? What would change about the
10 interrogatories? The good fair portion of our
11 interrogatories are entirely based on science, but,
12 again, the problem is we don't know what they have
13 in their files, and they tell us they're not even
14 sure what they have in their files, and so this is
15 why we need to go where we can go. Otherwise we're
16 going to be back here talking about this.

17 THE COURT: All right. Thanks.

18 well, folks, you don't know if you're -- if
19 it's complete. When are you going to know?

20 Ms. Gussack, I take it you're prepared to
21 address that?

22 MS. GUSSACK: I'm prepared to address a couple
23 of things, Your Honor, if I may.

24 One is that I want to go back a step and
25 point out that in response to your request about

1 cost efficiencies and avoiding repetitive and
2 duplicative discovery and hearings and decisions,
3 the panel made this coordinated proceeding stating
4 specifically in their order that "Plaintiffs in all
5 actions allege that the use of one or more of four
6 antidiabetic incretin-based medications, listing
7 them, caused them or their decedent to develop
8 pancreatic cancer. Centralization will eliminate
9 duplicative discovery, prevent inconsistent pretrial
10 rulings, particularly on such matters as rulings,
11 and conserve the resources of the parties, their
12 counsel, and the judiciary."

13 And while the plaintiffs are suggesting,
14 Your Honor, that this is an impossible situation and
15 that objections are running amuck, I'm mindful of
16 the fact that the plaintiffs have not gone to
17 Judge Dembin saying that they've been obstructed or
18 impeded or hindered. There's been an enormous
19 amount of meeting and conferring, an enormous amount
20 of document production. I think the parties are
21 capable of identifying what the reasonable scope of
22 scientific material is.

23 And while I can certainly be criticized for
24 not being a good plaintiff's lawyer this morning, I
25 think I can reasonably offer the Court some

1 assurances in response to what the plaintiffs are
2 suggesting. The plaintiffs are suggesting that they
3 need to have access to all of the internal email and
4 files of the company from marketing to regulatory
5 and the like in order to inform the central
6 scientific issue here, whether these agents caused
7 pancreatic cancer. And while it's -- I think it is
8 worth the Court's time, Your Honor, to listen to
9 this example of why I think that is so misguided.
10 In the plaintiffs' brief that they filed with
11 respect to their proposal around the case management
12 order, they reference that defendant Lilly in their
13 email files has an email in which their own
14 researcher admits that their real concern is not
15 whether their product causes cancer with the 14
16 percent, five-year survival rate even if caught
17 immediately, but whether regulatory officials and
18 the public might get wind of the risks of
19 incretin-based therapies ruining sales of the whole
20 family of drugs. And then they drop footnote 31 and
21 they tell the Court, "We didn't attach this
22 document, but it's available."

23 As counsel for Lilly I was very concerned.
24 I thought, "I have never seen such a document, and
25 that's a very strong statement." And so we dug out

1 the document. The document is a Dr. Anderson
2 commenting on a media release about Januvia, not
3 Byetta, in which there was -- I think the headline
4 that if -- I want to be very -- the headline said,
5 "Popular Diabetes Treatment Could Trigger
6 Pancreatitis, Pancreatic Cancer." A media report.
7 And Dr. Anderson's quote in her email is, "Dang, you
8 beat me to it. If this gets a lot of play, the
9 whole class of incretin-related drugs could be
10 dead," which seems like a pretty fair statement that
11 if this were true, that would be very problematic
12 for this class of medicines.

13 Is that evidence of general causation? No.
14 And the plaintiffs failed, unfortunately, to provide
15 the email train that followed by four hours
16 Dr. Anderson's comment that said, "Please ignore my
17 comments of earlier. They were loose responding to
18 a media report. They were not informed by the
19 scientific data."

20 So one, if you're going to use emails as
21 evidence or substitute for scientific data and the
22 issue of general causation, you would not be looking
23 at these kinds of emails nor do you need them to
24 frame the issue.

25 I think the Court has raised the right

1 question. What is it that's needed, and how long
2 should that take, and shouldn't that be the priority
3 issue that all of the parties direct their energies
4 to?

5 But to suggest that we need all of the
6 emails in the company in order to demonstrate that
7 there are issues around the science seems to be
8 unfounded.

9 The parties are fully capable, I can assure
10 Your Honor, of framing what discovery is needed in
11 order to address this issue. A substantial amount
12 of evidence is public. A substantial amount already
13 exists in plaintiffs' hands. The answer to the
14 question that was raised by counsel for the
15 plaintiffs, "How do we know what the rules are of
16 who is included in the study or excluded?" is in the
17 protocol for the study, which is in the NDA, which
18 is in their possession. If they have the
19 depositions that they think they need to take in
20 order to test or address the science, I'm confident
21 that that can be done as well in a reasonable time
22 period.

23 But I want to remind the Court that the
24 plaintiffs sought the MDL that we currently
25 participate in by stating to the panel that "we

1 anticipate that the experts that we need in these
2 cases would all be the same, that they would be able
3 to testify on behalf of each of the drugs, and so we
4 think it's important to have them together in one
5 court, so one judge has the ability to analyze the
6 cases, analyze the experts, and to see whether or
7 not those experts are allowed to testify." That's
8 page 5 of the transcript before the panel with
9 Mr. Thompson speaking. And I think equally
10 important is that Mr. Thompson said to the panel in
11 the argument, "Judge Battaglia has issued a very
12 aggressive case management order in the Scott case,
13 one in which, if it had been followed, expert
14 disclosures would be due in ten days." Now, we
15 recognize that Scott has been put to the side once
16 the MDL was formed, but Mr. Thompson was arguing on
17 behalf of plaintiffs. "These are terminally ill
18 plaintiffs. They need to have their day in court,
19 and we welcome an aggressive case management order."
20 we too share a concern that sooner rather than later
21 testing the central issue here is critical.

22 And to answer Mr. Shkolnik's comment about
23 the case-specific plaintiffs, I do want to point out
24 that terminally ill plaintiffs have in this
25 litigation the unique ability and information about

1 their medical providers, their medical history, and
2 the basic factual information we seek. And we do
3 not have the luxury of delay around getting that
4 basic factual information.

5 THE COURT: A couple other things. If you want
6 to defer to one of your colleagues on the defense
7 side, you can. But EMA is irrelevant?

8 MS. GUSSACK: No, Your Honor, I don't believe
9 that's what -- at least Lilly's objection to the
10 discovery was. The objection was to the extent
11 you're asking about foreign regulatory proceedings,
12 we don't think that's relevant, but we will respond
13 to this discovery following our meet and confer, and
14 I think the parties have agreed that objections
15 would be framed first and that discovery responses
16 would follow.

17 THE COURT: Because the EMA report we've heard a
18 lot about in Science Days, and I take it that's the
19 body of some of the science that somebody's going to
20 be using one way or another in their expert
21 analysis, so that stays true.

22 MS. GUSSACK: Certainly the report of the EMA
23 and their conclusions has been -- is publicly
24 available, and I believe the plaintiffs have, and
25 you're quite right. We believe that their analysis

1 is irrelevant.

2 THE COURT: But the degree to which there is
3 connection or involvement between any of the
4 defendants or all of them and the EMA in terms of
5 providing information, cooperation that resulted in
6 that study, that would seem to be discovery relevant
7 in terms of bias and the other studies, so I take it
8 there would be no objection to responding to those
9 questions fairly, would there?

10 MS. GUSSACK: Speaking for Lilly, I would agree.

11 THE COURT: Anybody else disagree on that
12 particular note?

13 MR. MARVIN: No disagreement, Your Honor.

14 THE COURT: When from the defense perspective,
15 or at least Lilly's perspective, will your responses
16 to this about this key issue be complete? When can
17 you certify its -- I know it's somewhat of a moving
18 target because you're probably still getting
19 adverse -- adverse what --

20 MS. GUSSACK: Event reports.

21 THE COURT: And so at some point we'd have to
22 draw a line in the sand and say, "Okay. As of
23 December 31st," or you all can pick a date, "that's
24 where we close the book and then make sure it's
25 complete to that point." You have to do that, but

1 when can we get to the point of saying from the
2 defense perspective, and you all may have a
3 different view, but from your perspective and Lilly,
4 when can we say, "well, we've given them everything
5 reasonably after the diligent inquiry on all of our
6 obligations in discovery"? It's not complete as of
7 a precise date.

8 MS. GUSSACK: Your Honor, that's a multi-faceted
9 answer. One is the New Drug Application is a living
10 document. So that as we engage with FDA and provide
11 them information, communicate with them, that is
12 added to the New Drug Application. So if there are
13 supplements since it was last produced to them, I
14 think we should -- "Here's the cutoff date, and we
15 will supplement up to that date." And it should be,
16 at least from our perspective, that would seem to be
17 the reasonable way one would do it.

18 The other component of your question,
19 though, speaks to, I think, production from other
20 sources beyond the regulatory materials.

21 THE COURT: well, no, I'm talking in terms of
22 Lilly being in a position to say, "Our responses to
23 your discovery as of a certain date," or however you
24 frame it, "are now complete, as complete as anything
25 is in the world."

1 MS. GUSSACK: I think, Your Honor, if we had
2 clarity about which custodians we had -- we were
3 produced from and through what -- and cutoff date,
4 I'm confident, from Lilly's perspective, that that's
5 something that could be done within several months'
6 time, so that we could assure ourselves that we had
7 been exhaustive in our production.

8 THE COURT: And the last question I'll bother
9 you with for the moment, and then I'll turn to the
10 other defendants, is this issue about a marketing
11 document talking about, "well, with that signal
12 detection, that's not good, and we aren't going
13 to -- this needs to be dealt with in one way or
14 another." How is that going to surface, in your
15 view, of a restriction on defendants' obligation to
16 respond to discovery as to general causation? Is
17 that going to be something you feel would be
18 responsive to a request that, say, you provide all
19 documentation with regard to any signal detection
20 that was excluded from the study? Is that going to
21 be responsive?

22 MS. GUSSACK: Well, Your Honor, we think about
23 these issues in terms of function of the employee,
24 so that if the discovery request is to marketing --
25 marketing plans or marketing communications around

1 Byetta, that would retrieve a certain kind of likely
2 marketing kinds of documents. I don't think we
3 have, you know, a department of documents of
4 marketing talking about signal detection so they can
5 go to a file and say, "Let's produce that." I think
6 the point is that if we prioritize the focus on
7 where the likely information is that the plaintiffs
8 believe they need to frame this issue, then we will
9 be able to in a reasonable time frame focus in, and
10 I would point out, and I think it's really the
11 central issue, an email talking about whether a
12 marketing person accurately described, you know,
13 adverse event reports isn't a substitute for
14 affirmative evidence that the plaintiffs need to
15 demonstrate their proof of a causal connection
16 between these medicines and pancreatic cancer.
17 Emails will not substitute for that kind of
18 scientific data.

19 THE COURT: No, but if there is an appropriate,
20 focused question with regard to a factor in the
21 general causation analysis, Lilly would be looking
22 at it from the companywide standpoint or would you
23 just be looking at it from the science room? I was
24 hoping you'd be looking at it to the extent that
25 it's practicable from a companywide standpoint.

1 would you look for that information, whether it be
2 in marketing or operations or in some other
3 department? I would hope --

4 MS. GUSSACK: We have been looking across -- the
5 discovery, I would say, has been very broad. We
6 have attempted in some meet and confers that are
7 ongoing to -- and I think even this week to engage
8 in discussions that would allow us to target where
9 we should be looking and what's a reasonable frame
10 of reference to make those searches, but I don't
11 think that there's any suggestion that we would be
12 excluding one component of the company from making
13 those kinds of searches for responsive information.

14 THE COURT: Okay. Well, moving to your right,
15 Mr. Marvin.

16 MR. SHKOLNIK: Just one follow-up as it relates
17 to Lilly alone, and I just want the record to be
18 clear, if we could.

19 THE COURT: Sure.

20 MR. SHKOLNIK: The interrogatory and the
21 question and answer we're talking about was not
22 generic other regulatory bodies. Just so it's
23 clear, the question was -- and it's the same
24 question to each defendant. "Has any employee,
25 officer, director, agent, contractor, director, key

1 opinion leader," which is a term of art, "member of
2 the speakers bureau, advisory board member, or
3 scientific advisor of yours corresponded with or
4 supplied information or data to the EMEA about or in
5 connection with its 2013, quote, assessment report
6 for GLP-1 based therapies, closed quotation. If so,
7 state who the person is."

8 And to that question the response from
9 Lilly was they further object to it as overly broad,
10 not reasonably calculated to lead to discovery of
11 admissible evidence, and it seeks information
12 regarding regulatory matters not at issue in this
13 litigation.

14 This was not a -- we did not shoot with a
15 shotgun. We went directly to the document that we
16 heard no less than 50 times about during Science Day
17 over two days and wanted to find out who were the
18 companies?

19 THE COURT: And they just said they don't feel
20 that that's outside the scope of relevance if -- and
21 so I think you could expect to have some answers
22 with regard to what was supplied or interaction may
23 have led to this study which supports their
24 position.

25 MR. SHKOLNIK: I just wanted to be clear. The

1 question we asked was not a general shotgun to
2 agencies.

3 THE COURT: I didn't expect that it was.

4 MR. SHKOLNIK: Thank you, Your Honor.

5 THE COURT: So Mr. Marvin, you want to -- would
6 your answers be any different than Ms. Gussack's in
7 terms of substance?

8 MR. MARVIN: Just a couple quick points. First
9 on marketing, if the marketing department has --
10 conducts some kind of study related to safety,
11 whether it was a postmarketing study or whatever
12 kind of study we've been looking for that, and we
13 would continue to look for that, and if there is
14 such a study by marketing about the safety of the
15 product, we'll produce it.

16 The second point, we have received over 147
17 document requests, and those requests have countless
18 subparts. When I say "countless," we tried to count
19 up the number of subparts and finally gave up in
20 trying to determine how many subparts there were.
21 Suffice it to say, it was 47 pages of document
22 requests. And if we embark on the road of just
23 going ahead and in normal course and having all kind
24 of productions of millions and millions of pages,
25 various disputes about various issues, we will be

1 going down a road that's going to take us a lot of
2 time and spending a lot of money without addressing
3 the threshold issue.

4 And the third point is that -- and we -- we
5 have mentioned this a couple of times, and we
6 continue -- and I want to emphasize it, I guess, is
7 that if there are gaps in our production, we're
8 willing to sit down with the plaintiffs and talk
9 about filling those gaps. If there are targeted
10 requests relating to causation that they want us to
11 explore, we're willing to sit down and discuss it
12 with them. So this is a process, and it's a process
13 that we're willing to cooperate with the plaintiffs
14 in getting this kind of an issue addressed.

15 THE COURT: Okay. And from Mr. Goetz from
16 Amylin, any difference you want to point out or
17 anything you want to supplement Ms. Gussack was
18 talking about?

19 MR. GOETZ: No, I agree with Miss Gussack and
20 Mr. Marvin. We don't have any discovery disputes
21 before Judge Dembin right now. What you heard about
22 in deposition last week, I'll tell you, is
23 inaccurate, but I don't think there will be an issue
24 here because there is no issue that's been raised
25 before Judge Dembin. We'll move forward.

1 I was taken by the fact that the plaintiffs
2 were able to tell Your Honor that they had found a
3 specific person in a study who had been excluded,
4 and that's because of the enormous quantity of
5 documents we've already produced. To bring this
6 home, I'm told by my paralegals if you divide the
7 number of pages produced by 3,000 of about how many
8 boxes have been produced, so you take that 6.5
9 million pages that Ms. Gussack started out with,
10 that works out to roughly 2,200 boxes of material.
11 So we've gone a long way in this, and so when you
12 ask when will we be done, I hope soon, and I think
13 for general causation, we are on the timeline that
14 Ms. Gussack said, but we've produced so much that
15 you're getting this kind of a granular level from
16 the plaintiffs already in these proceedings.

17 THE COURT: Okay. And then Ms. Levine.

18 MS. LEVINE: Yes, thank you, Your Honor.

19 I agree with everything my colleagues have
20 said, but I'll just add a few points. The Court
21 seems to understand the efficiencies of focusing
22 first on the science and what the defendants want is
23 the sequencing. That's what's really important. We
24 are willing to give plaintiffs the time that they
25 say that they need to deal with the science. We may

1 disagree to what extent it involves marketing or
2 other issues, but we haven't really had any major
3 discovery disputes.

4 we're meeting with the plaintiffs this
5 afternoon. we've asked them what they want. we're
6 talking about those issues. we think that once the
7 parties hear from the Court about how the Court
8 wants to sequence the events for discovery and if
9 the Court explains that general causation or science
10 issues come first, then the parties can figure out
11 what that discovery schedule looks like and what
12 needs to be done and prioritize and focus to get the
13 discovery the plaintiffs need in order to put
14 science first.

15 They have experts lined up, I'm sure. And
16 those experts can tell them what they think they're
17 missing from our files, and we can sit and talk to
18 the plaintiffs very transparently about what we
19 have, what we can produce, and what timeline we can
20 do that.

21 I think that the discussions from
22 plaintiffs talking about various discovery issues
23 and how to separate science from nonscience is
24 really not at issue.

25 we do think that that is easily done, and

1 if not easily done, we're willing to sit at the
2 table. Magistrate Dembin has been very willing to
3 talk to the parties when issues arrive.

4 I just want to also make a point about the
5 allegations that we're asking the plaintiffs to
6 scorch the earth on their side about plaintiffs'
7 side of discovery. All that we have right now for
8 us to receive information about plaintiffs is the
9 plaintiff fact sheet. Magistrate Dembin has issued
10 an order, an opinion, on that. We're basically just
11 getting the equivalent of written interrogatories
12 and document requests about their medical history,
13 their drug use, their prior medical conditions.
14 There hasn't been depositions of physicians, of
15 their treating doctors, of even the plaintiffs.
16 There have only been a handful of extremis
17 depositions to date, and none of the defendants has
18 rejected a request to undertake those depositions
19 that are requested by the plaintiffs' counsel, so I
20 think there's a -- I just want the Court to
21 understand that we're taking on the burden, a heavy
22 burden. Even if the Court focuses the parties on
23 science, it's still a massive amount of discovery,
24 and we're willing to undertake that. So we need to
25 really figure out the timing as long as the parties

1 understand the sequencing.

2 THE COURT: Okay. Well, I do think that we need
3 to direct the -- I guess we'll call it the
4 plaintiffs' discovery to this issue of general
5 causation. And I -- you know, the problem I see is
6 we label things differently. If it's a marketing
7 document, we seem to think that may not be within
8 the limited or more directed scope, but indeed I
9 think it is. I think you need to look at what
10 might -- a document in logic to prove or disprove
11 that the drugs caused or otherwise adversely
12 impacted development of pancreatic cancer in a
13 patient, and whether it comes from the marketing
14 office or the science lab or somewhere else, it's
15 all fair game, as I see it, but I think that we do
16 need to focus on the general causation, get to the
17 point where we get a complete package as of a date
18 certain so we have a static base with which to
19 evaluate both the bona fides of the experts and
20 then, of course, the issue of the day or of the
21 case, and with that in hand we quickly move there to
22 the other issues with regard to representations,
23 misrepresentations to the public, or anything else
24 that goes into the causes of action that have been
25 stated, and then start trying the cases and figure

1 out what it all means.

2 So I'm going to order that we phase the
3 case dealing with the general causation issue. No
4 one seems to think we need to split GLP and DPP-4,
5 and so fair enough.

6 And I do think it's important, and I hadn't
7 thought about it when it was first mentioned, but
8 the plaintiffs are a finite resource, and,
9 unfortunately, if they have the pancreatic cancer,
10 they are -- there's some risk that they may not be
11 here at the end of the day. So I do think that that
12 discovery, limited as it is, should continue as it
13 has so that we have the benefit, not only the
14 defense but the Court ultimately or trier of fact,
15 of the information related to these folks that are
16 afflicted to deal with in an appropriate manner. I
17 think the extremis deposition process needs to
18 continue for that very same reason. We don't want
19 to lose that resource. I mean as I -- if we can get
20 a complete date, I see no reason that we couldn't
21 start the process of designating, and experts
22 disclosing their reports and working information,
23 deposing them, and then setting up a date for
24 Daubert MSJ hearings. It sounds to me like the
25 defense is all going to take it in terms of a joint

1 approach as opposed to manufacturers or not, but you
2 don't have to make that decision at the moment, but
3 if it's going to be multiple summary judgments, we
4 may have to talk about are we going to hear them all
5 in one day or are we going to break up the argument
6 or whatever, but I don't see any reason we can't be
7 able to go to trial in early 2015 if we get this
8 first lump out of the way. It's going to come up
9 sooner or later, and I think there's great utility
10 in focusing your all efforts in the general sense on
11 this set of science -- this scientific issue that we
12 call general causation. Are the drugs a substantial
13 factor in bringing about pancreatic cancer or
14 accelerate or something else? And that's -- I'm
15 throwing it out. It's a loose definition. You may
16 want to define it yourselves jointly, but I think,
17 you know, I can start setting dates, but it might be
18 useful for you to have your conversations and
19 determine when we can get completion because I don't
20 want experts to have to do Report Number 2 and
21 Report Number 3 because it's a rolling production.
22 My view is we get the record, quote, unquote,
23 complete, the experts stand and deliver on their
24 reports, and undertake the deposition process, and
25 we deal with the motion.

1 So yes, sir, Mr. Kennerly.

2 MR. KENNERLY: Yes, Your Honor. The reason I
3 stood up is when we're talking about how to schedule
4 discovery going forward, one of the things we've run
5 into, and they mention there's no motion in front of
6 Judge Dembin. His policy is he has a lot of back
7 and forth between counsel, and I'm not saying it's
8 good or bad, but he has a lot of back and forth
9 between counsel, and when we finally reach an
10 impasse, we're supposed to submit a brief that
11 raises what our issues are going to be, so on and so
12 forth, and the question I have for Your Honor is
13 should we ask Judge Dembin to modify that? Should
14 we ask Your Honor to modify that because if we're
15 trying to move on a streamline schedule, that's
16 going to have a big impact on us because we send out
17 a request, it's going to be minimum 90 days, more
18 like 120 days until there's an actual motion in
19 front of the Court briefed and ready to go, and so
20 that's one of our concerns in that's still going to
21 be there or not.

22 THE COURT: well, I imagine -- do both sides
23 share some concern that maybe the current status quo
24 might be slow such that an expedited or more
25 streamlined dispute resolution process would be

1 helpful?

2 MS. LEVINE: No, Your Honor. Speaking for
3 Novo -- I think I can speak for all of the
4 defendants -- we don't have the same concern.
5 Magistrate Dembin has had his proverbial door open
6 to us. We've called his chambers when we've had a
7 dispute. He's told the parties if we need
8 expedited, we submit a brief, and briefing is five
9 days for one side and five days for the other. He's
10 ruled very promptly, and if there's any type of
11 emergency issue prior to a deposition or some issue,
12 we have no problem jointly calling the Court and
13 figuring out a process at that time. I think it's
14 premature, and, frankly, Judge Dembin is not here to
15 raise it, so --

16 THE COURT: But he's doing criminal duty, so he
17 couldn't be.

18 Let me say this. Had you both agreed, I'd
19 say come up with an expedited plan and we'll go with
20 it. I'll be keeping an eye on things, and if I see
21 there's discovery issues that are languishing for a
22 month or two, I'm not going to sit for that. I'll
23 intervene, and we'll set up an expedited process.
24 So let's see. I mean I think he has every intention
25 of being efficient and timely, and in my view, since

1 it's my case at the end of the day -- it's your
2 case, but from the Court's perspective, it's my
3 case, if I think it's taking too long, then I'll get
4 involved, and we'll shorten it. You've got that
5 assurance.

6 MR. KENNERLY: Thank you, Your Honor.

7 THE COURT: So but that brings us back to the
8 question. I mean do we prophylactically say get
9 discovery complete in 30 days, and then we'll start
10 the process of expert designation and then -- what I
11 would propose we do is we designate and then we
12 disclose in two steps so that nobody gets sandbagged
13 or feels like they're going to need additional time
14 because they haven't anticipated that you were going
15 to need an astrophysicist or something else.

16 MR. HOERMAN: I believe we're going to need
17 depositions as well. You're contemplating no
18 depositions or custodial files. I think there's a
19 process before the defendants, and, unfortunately,
20 I'd love to go quick if we can, but there's just
21 some things that are going to take time. We'll do
22 our best, but we need to build in enough time.

23 THE COURT: All I'm saying is if I assumed it
24 was complete in 30 days --

25 MR. HOERMAN: The written discovery.

1 THE COURT: I was just talking about the general
2 causation discovery, but don't worry, you'll get
3 time to do what you've got to do, but we have to get
4 to the point where we can define what that date is
5 because otherwise if I start compelling reports off
6 of a best hoped for date, there is -- you're either
7 going to have to push them back or we're going to
8 have to have supplementals that just will bog us all
9 down.

10 Ms. Gussack.

11 MS. GUSSACK: Although I don't have the
12 agreement of my colleagues, let me suggest the
13 following: would it be useful if we took an
14 opportunity -- well, would it be useful to -- if
15 we -- if I'm hearing Your Honor correctly, aim for
16 that we want expert discovery concluded by November,
17 say, and give us an opportunity to work with counsel
18 for the plaintiffs to erect a discovery program that
19 makes sense so that we can have designations and
20 then disclosures leading up to motions by November.
21 I think if you give us the date that we're working
22 backwards from and then allow the parties to meet
23 and confer about what schedule makes sense, we may
24 be able to narrow the disputes. I'm not sure that
25 that's a shared view, but it might help us get

1 there.

2 THE COURT: well, I was thinking about -- I
3 don't hear anybody protesting on the defense side.

4 From the plaintiffs' side, is that a way to
5 do it?

6 MR. SHKOLNIK: We're very happy to have an
7 aggressive schedule for discovery. We have had a
8 couple of 30(b)(6) witnesses that have gone nowhere.
9 Depositions. To suggest that we can have full
10 disclosure of experts by November with depositions
11 is a very nice follow-up to the 60 days they
12 originally suggested, but it's almost -- I mean to
13 say it's unreasonable is mild. For us to get
14 discovery from the defendants complete before the
15 end of the year would probably be a Herculean task.
16 I'm being very candid. Even if we're saying science
17 on whatever science is as the defendants want to
18 define it today. Just to get that -- the hardcore
19 discovery, the custodial files and the depositions
20 of the science people, for example, with four
21 defendants, we may want a director of science or
22 medical director. That may be four different
23 witnesses if over a period of time they have
24 replaced that employee. We're going to need the
25 science employees, and we could be talking 20

1 depositions per party even just on the generic
2 causation issue.

3 THE COURT: Except keep in mind this isn't state
4 court, so we're not talking about person most
5 knowledgeable. We're talking about a 30(b)(6),
6 which the defense can pick and bring up to speed and
7 doesn't necessarily mean you get the science
8 director 20 years ago. You get someone that knows
9 that information. So make that distinction clearly
10 or keep it clearly in mind that it's not a state
11 court type of a process. It's a 30(b)(6), not a
12 PMK. So to some degree, that request to have every
13 science director over the last ten years is going to
14 fall on deaf ears if I have anything to say about
15 it. It's going to be someone that knows, can
16 testify on behalf of all of those science directors
17 during that period, and that's their obligation to
18 provide, and if they don't, then we deal with that.

19 But it strikes me that why don't we break
20 it down -- can we break it down -- I'm asking this
21 of the defense -- as to a date to get your
22 disclosures as far as -- your discovery responses,
23 your production, your answers to whatever
24 interrogatories, get those complete, and then --
25 because you can control that presumably. You know

1 when you'll have it done. And then from there we
2 can set a period for follow-up depositions through
3 that plaintiffs think are necessary and then we
4 start triggering these other things. I mean I had
5 hoped to get the motions filed by, you know,
6 October, November and heard early in the year and
7 start trying cases, but maybe that's optimistic, and
8 that's the problem where things aren't complete, and
9 so we need to get that. So what if we try the
10 targeted date for the defense to get complete on the
11 written discovery, set aside time for depositions,
12 and let's face it. Even in the best of cases, you
13 do your best to set a schedule, and sometimes stuff
14 happens, and so we have to adjust modestly
15 hopefully, but you might have to, but if we get the
16 document discovery done and we've set up the
17 deposition window, and, of course, the deposition
18 window or even the document discovery is ongoing, we
19 can start saying who the experts are, although you
20 probably already know, and then after we get the
21 discovery in the bag on this, have the reports
22 follow, and when the reports are done and
23 depositions of the experts are done, we can target
24 the filing date for motions. And the problem with
25 setting an end date is it doesn't account for what

1 we don't know, and these are the -- you're setting
2 it in a prospective fashion, but it's a little
3 closer.

4 So can the defendants commit individually
5 or collectively where we can get this document
6 discovery complete relative to some -- I guess it's
7 going to take a negotiation as to some point in time
8 where we draw a line in the sand as to -- as of
9 date, and --

10 MR. HOERMAN: If I may, Judge, oftentimes these
11 take the role of them producing custodians that
12 we've agreed upon, so they might produce six or
13 seven key witnesses that they find are key because
14 we don't know yet who the key witnesses are, and we
15 get those documents, we review those documents. It
16 may end up that those are folks we don't want to
17 depose or need to depose, but after reviewing those
18 documents, we figure out that Joe Smith is in a
19 different department that's critical to our case,
20 and then we order custodial files. So this process
21 of just disclosing documents, I'm a little concerned
22 about it.

23 THE COURT: But you don't get there until they
24 give you the documents.

25 MR. HOERMAN: But what we usually do, and if you

1 look at Novo Nordisk's response to our production
2 request, their response is, "Nothing will be
3 produced until we've sat down and discussed which
4 custodians are going to be produced." They'll then
5 go through their files and figure out -- and do the
6 search terms and then produce to us the documents of
7 those custodians, and then we'll come back and say,
8 "We need these three or four more." That's what's
9 been contemplated in discussion with the defense.
10 I'm sure they'll agree with that. And that process
11 just takes time, and so I'm trying to just be very
12 practical here because I don't want to come back in
13 with a problem four months from now or five months
14 from now because we're just still in the custodial
15 process and not yet through the deposition process.
16 So I think practically speaking, and I know the
17 Court is inclined to try to get this done quickly,
18 the custodial process is in its infancy, and we'll
19 try to push it as fast as we can, but 30 days for
20 production, I'm not sure how it's actually going to
21 work out.

22 THE COURT: I don't know. That's what I'm
23 asking them about.

24 MR. MARVIN: If I may make a suggestion with the
25 Court's guidance, I would like motions by October or

1 November. I think we could sit down with the
2 plaintiffs, now that we know which fork in the road
3 is going to be taken, and develop a schedule that
4 would allow us to meet that target. And that is
5 something that we could sit down with them within
6 the next ten, 20 days and try to work out so that we
7 do have a schedule to meet that target.

8 THE COURT: Isn't there a discussion between the
9 document requests and the interrogatories and what
10 not and the custodial depositions that the
11 plaintiffs are talking about? Isn't that Step 2 --
12 at least a two-step process?

13 MR. MARVIN: Yes, it is.

14 THE COURT: So I think it's incumbent upon you
15 folks to figure out -- I think you all need to come
16 to collectively a decision where we put some marker
17 in the sand as to a cutoff date for purposes of
18 data, it would seem to me. Otherwise, you're going
19 to have this problem unless there's something major
20 that comes up in this scientific field about this,
21 we're going to have a situation where the experts
22 are trying to pin down a moving target, and so is
23 the Court. So it seems like you should have a
24 working forward date, and the defendants need to get
25 to the point where they can certify where they have

1 produced all of the responsive documents with regard
2 to these issues, and then you folks can confer. I
3 see no reason that you can't confer and just figure
4 out which custodians or other follow-up witnesses
5 you might need on this basic data, all of which goes
6 to the experts and they do their thing and come up
7 with their reports. So I think you need to follow
8 that format, and I think what drives it in response
9 to the plaintiffs' concerns is when the defense has
10 completed at least with Phase 1 and then you move
11 into Phase 2. Maybe it's a good idea, as Mr. Marvin
12 suggested, to let you talk and revisit this issue in
13 a couple of weeks, and it also may be a good idea
14 that we assume as we set a date for completion we
15 coincide that with a telephonic status conference,
16 check it off, and then realistically reevaluate the
17 next date, and then revisit it, and evaluate the
18 next date to the point that we can say okay. Let's
19 get the expert reports, and then we lock in a
20 briefing and hearing dates, which may or may not
21 fall as the Court and defense seem to have come up
22 with, maybe more like the plaintiff appears will
23 happen or something else entirely.

24 So from the plaintiffs' perspective, what
25 are your thoughts about doing that, you talk and we

1 come back in two weeks and at least address
2 completion dates and prospective follow-up discovery
3 on this general causation which I'm defining as
4 relevant evidence on whether or not the drugs cause
5 pancreatic cancer in whole or in part or whatever?

6 MR. JOHNSON: Your Honor, from the plaintiffs'
7 perspective, I think it's a very workable
8 resolution. And it's got the added benefit of
9 really allowing the defendants to control their
10 schedule, and they can control how fast they get to
11 their ultimate causation hearing by how quickly they
12 comply -- how appropriately they comply with the
13 discovery requests.

14 THE COURT: Exactly.

15 MR. JOHNSON: The plaintiffs' perspective, I
16 think it's a very reasonable and workable
17 suggestion.

18 THE COURT: And maybe my notion of a cutoff date
19 is not realistic for your scientific issue, but it
20 seems to make some sense in the scheme of things,
21 but something to talk about. And I'm not a big one
22 for not having a finite schedule right now, but it
23 seemed like we've got -- we've got to get from the
24 defense a completion date for the document
25 discovery, and then we can set a reasonable period

1 to do the follow-up discovery, and, you know, once
2 the discovery is in the bag, we can move real
3 quick -- these experts should be -- I'm sure are
4 already evaluating what's out there, and we should
5 be able to get this position to at least get motions
6 on file by year end and maybe heard in January and
7 jump in from there.

8 So why don't we talk about letting you
9 folks confer and as you are going to do anyway
10 today. In fact, if you want to start when I leave
11 the bench and do it here, you're welcome since
12 you're here, or if there's a better place, go there.
13 And why don't we -- why don't we then set the
14 follow-up -- I suggest the phone since so many of
15 you folks travel, and it hopefully will be concise,
16 but how about something like -- two weeks to the day
17 take us to -- wow. March 11th. How about -- I'm
18 going to be in a big tax trial. How about if we
19 have an 8:30 phone conference on March 11th or some
20 day that week that the -- your relative key people
21 can participate in or if you need to check back with
22 your schedules and call back to Crystal and clear a
23 date, we can do that.

24 MR. GOETZ: Two weeks is actually March 4. That
25 would work for us.

1 THE COURT: Oh, March 4. Oh, I'm in a criminal
2 trial that day. Okay. So about 8:30 for the -- for
3 that purpose.

4 MR. SHKOLNIK: Your Honor, is it possible to
5 have a call-in conference at the end of the day for
6 the court?

7 THE COURT: Oh, yeah.

8 MR. SHKOLNIK: Because for those of us on the
9 East Coast, the 8:30 will be a 5:30 in the morning
10 call. I've been through a number of those. Oh,
11 10:30.

12 THE COURT: We'll be having an early lunch. But
13 having said that, I don't mind 4:30 either.

14 MR. SHKOLNIK: The other way around was fine.
15 My math was wrong.

16 THE COURT: Either your lunch hour or your
17 cocktail hour.

18 So enough of the folks on the plaintiffs'
19 side good with March 4 at 8:30?

20 MR. SHKOLNIK: Yes.

21 THE COURT: The defense side?

22 MS. LEVINE: Yes.

23 THE COURT: Okay. So just to recap, we're going
24 to focus -- we're going to narrow discovery on the
25 plaintiffs' -- of the plaintiffs' discovery as to

1 the defendants to this issue of general causation as
2 we've tried to create a definition for it.

3 Plaintiffs will continue to respond to the fact
4 sheets and so forth so we don't lose that critical
5 data, and the extremis deposition process will
6 continue, and then in two weeks, we will have a
7 phone conference where hopefully the defense will be
8 able to project its collective complete date and you
9 folks have talked about how we sort of cap the data,
10 whether it is a -- you know, as of date or whatever.
11 I think leaving the potential that something --
12 there's some scientific breakthrough that might
13 alter that, but so we can lock in that completeness,
14 and then what we'll talk about on the 4th is we'll
15 confirm that you've done all of that, we'll put that
16 date in an order as to completion, we'll target a --
17 the follow-up discovery issue, this custodial issue
18 that we were talking about, and set another status
19 conference to monitor how that's done, and when
20 we're confident that we have a completion date for
21 that, be prepared to quickly designate your experts,
22 and then thereafter disclose, oppose, and then we'll
23 keep it up for the motions. So we'll set more dates
24 as we get more done so we don't have to revisit the
25 dates, and if there seems to be some logjam with

1 discovery issues, then we'll be watching the docket
2 and watching those and decide whether or not we need
3 to change the status quo on how we resolve those or
4 not, and I have every confidence Judge Dembin will
5 put his utmost attention to this and move it. And I
6 will -- he'll get wind of all of this by virtue of
7 the order I issue.

8 So that's the plan at the moment. Is there
9 anything else from the plaintiffs' side? The
10 defense side?

11 MS. LEVINE: Your Honor, do you want the parties
12 to jointly submit a proposed schedule to you prior
13 to March 4th to discuss it or do you want to discuss
14 the proposals at the hearing?

15 THE COURT: well, if you can agree on a
16 schedule, then send it in. If you can't agree, then
17 let's just talk about it. Okay? Because you can
18 tell me in a few words what's in most of that stuff.
19 But it really is -- you guys say we can do it by X,
20 that's what we're looking for, and then from there,
21 other things will fall into place. As the
22 plaintiffs' said, you control a lot now where we get
23 to this ultimate summary judgment issue by getting
24 your ducks in order, and then we'll see how we go
25 with that. But talk -- I mean your talk should

1 include amongst yourselves your completeness dates
2 and the plaintiffs to be able to be affordably
3 benefit who you think that is, but also what you all
4 anticipate you'll need in this follow-up discovery,
5 whether it's the custodian names or otherwise. And
6 keep in mind what I said about the difference
7 between 30(b)(6) and PMKs, and, you know, we'll
8 continue to give you dates as we get success. I
9 think that's the best way to not have to revisit
10 things.

11 So anything else on the defense side? How
12 about on the plaintiffs' side?

13 MR. SHKOLNIK: No, Your Honor.

14 THE COURT: well, thank you all very much.

15 MS. LEVINE: Thank you.

16 THE COURT: Let us know what the call-in
17 arrangement is and who all anticipates who's going
18 to be on the call. That will assist the reporter.
19 I'll take the bench promptly at 8:30 on the 4th and
20 let the trial wait until we complete that step
21 because we are giving obvious priority to you folks
22 in this major piece of litigation, so thanks very
23 much. Have a good day. We'll talk to you soon.
24 we'll be in recess.

25 (The proceedings were concluded.)

1 UNITED STATES OF AMERICA
2 SOUTHERN DISTRICT OF CALIFORNIA
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8 I, Dana Peabody, CSR No. 6332, an official
9 reporter pro tempore of the United States of
10 America, Southern District of California, hereby
11 certify that I reported in machine shorthand the
12 proceedings had in the above-entitled cause, and
13 that the foregoing transcript is a full, true, and
14 correct transcript of the said proceedings held on
15 February 18, 2014.
16

17 Dated at San Diego, California, this 19th day of
18 February, 2014.
19
20
21

22 /s/ Dana Peabody

23 _____
24 Dana Peabody, RDR, CBC, CCP
25 CSR No. 6332